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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,415	02/10/2004	Malcolm Wilson Moon	PC23546C	9923

7590 12/29/2005

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EXAMINER	
SAEED, KAMAL A	

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/774,415	MALCOLM MOON	
	Examiner	Art Unit	
	Kamal A. Saeed	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-107* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *60-78,87-95 and 107* is/are allowed.

6)☒ Claim(s) *49-59,79-86 and 100-106* is/are rejected.

7)☒ Claim(s) *96 -99* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

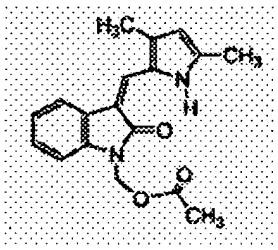
1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 01/23/04; 01/29/04 & 02/10/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 49-107 are currently pending in this application.

Response to Restriction

Applicants' election to Group I, claims 49-99 , directed to a product, and the species of



,described in **Example 2**, page 64, in response filed on 10/07/2005 is acknowledged. The restriction between the compounds, the method of use and method of preparation is hereby withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper time wise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 49-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6of U.S. Patent No. 6,716,870 B2, since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent. Although the conflicting claims are not identical, they are not patentably distinct from

each other because both sets of claims are drawn to the same art recognized subject matter. A reference anticipating one set of claim will render the other obvious and it would have been obvious to one of ordinary skill in the art at the time of the invention was made since US Patent No. `870 teach the generic compound which is an analog of the instantly claimed compound. The instant claims differ from the reference by reciting a specific species and a more limited genus than the reference. The instant compound is so closely related structurally to the analogous compound of the reference as to be structurally obvious therefore in the absence of any unobviousness or unexpected properties. One of ordinary skill in the art would be motivated to prepare the compound since there is an exemplary teaching to prepare the claimed compound in the prior art. The motivation to make the claimed compound derives from the expectation that structurally similar compounds are generally expected to have similar properties and have similar utilities. In re Gyurik, 596 F. 2d 1012, 201 USPQ 552 (CCPA 1979). Applicants should note that a generic teaching is grounds for obvious type double patenting rejection. In looking at the instantly claimed compound as a whole, the claimed compound and its uses would have been suggested to one skilled in the art unless unobvious or unexpected results can be shown.

Claims 79-86are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6of U.S. Patent No. 6,482,848 B2, since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to the same art recognized subject matter. A reference anticipating one set of claim will render the other obvious and it would have been obvious to one of ordinary skill in the art at the time of the invention was made since US Patent No. `870 teach

the generic compound which is an analog of the instantly claimed compound. The instant claims differ from the reference by reciting a specific species and a more limited genus than the reference. The instant compound is so closely related structurally to the analogous compound of the reference as to be structurally obvious therefore in the absence of any unobviousness or unexpected properties. One of ordinary skill in the art would be motivated to prepare the compound since there is an exemplary teaching to prepare the claimed compound in the prior art. The motivation to make the claimed compound derives from the expectation that structurally similar compounds are generally expected to have similar properties and have similar utilities. In re Gyurik, 596 F. 2d 1012, 201 USPQ 552 (CCPA 1979). Applicants should note that a generic teaching is grounds for obvious type double patenting rejection. In looking at the instantly claimed compound as a whole, the claimed compound and its uses would have been suggested to one skilled in the art unless unobvious or unexpected results can be shown.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 100-106 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case, applicants are claiming a method of treating "cancer", "infectious diseases", and "metabolic disorders". There are numerous cancer, and infectious diseases. Infectious diseases include bacterial infections (pneumonia, sexually transmitted diseases, skin diseases, endocarditis, bactermia etc), viral infections (meningitis, bronchiolitis, sexually transmitted diseases, hepatitis, central nervous system infections etc) and fungal infections. Metabolic diseases include diabetes, lipid metabolism, protein metabolism etc. The nature of pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. As defined the compound reads on treating all "cancer diseases", "infectious diseases" and "metabolic diseases" which is broader than the enabling disclosure. The compounds, which are disclosed in the specification, have no pharmacological data regarding the treatment of viral or bacterial infectious diseases. The specification, in page 54, lines16-21, states that "the compounds of the instant invention can also

be used as anti-infective agents", however the specification is short of any data (animal models, in vitro or in vivo testing) in regards to all "infectious diseases". It is suggested to delete "infectious diseases" to obviate the rejection.

Because of the unpredictability associated with the treatment of cancer and viral infectious diseases a greater amount of evidentiary support is needed in order to fully satisfy the requirement of 35 USC 112, first paragraph, that the applicant provide sufficient guidance as regards "how" to use the invention. The compounds drawn to the treatment of cancer, metabolic diseases are deemed deficient for the following reasons. It has not been in the specification that the testing protocol used is accepted in the art as being predictive of the utility alleged.

Additionally, "cancer" is a general term that embraces many different diseases, for example, leukemia, lymphoma, sarcomas and so forth. As defined, the compounds read on treating all types of "cancer" which is broader than the enabling disclosure. Chemotherapeutic agents are frequently useful against a specific type of cancer or neoplasm and especially with the unpredictability in the state of the art there are no drugs broadly effective against all forms of cancer, (Carter, S.K. et al., Chemotherapy of Cancer; Second Edition; John Wiely & Sons: New York, 1981; Appendix C). The compounds, which are disclosed in the specification, are used in treating human cervical adenocarcinoma (see page 24, example 2). It is suggested that the claim either be limited to the diseases actually contemplated in the specification or enable the full range of this term.

Allowable Subject Matter

Claims 60-78, 87-95, 98, and 109 are allowable over the prior art

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamal A Saeed whose telephone number is (571) 272-0705. The examiner can normally be reached on M-T 7:00 AM- 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

Communication via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signiture, may be used by applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR only. For more information about the pair system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

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PRIMARY EXAMINER